DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 86E-0098]

Determination of Regulatory Review Period for Purposes of Patent Extension; Cefotan

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Cefotan and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESS: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) generally provides that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under that act, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Cefotan (cefotetan disodium), which is indicated for the therapeutic treatment of a variety of infections caused by certain organisms. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Cefotan from Yamanouchi Pharmaceutical Co., Ltd., and requested FDA's assistance in determining the patent's eligibility for patent term restoration. FDA, in a letter dated March 17, 1986, advised the Patent and Trademark Office that the human drug product had undergone a regulatory review period and that its active ingredient, cefotetan disodium, represented the first permitted commercial marketing or use of that active ingredient. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Cefotan is 1,546 days. Of this time, 839 days occurred during the testing phase of the regulatory review period, while 707 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 507(d) of the Federal Food, Drug, and Cosmetic Act became effective:* October 4, 1981. FDA verified the applicant's claim that the notice of claimed investigational exemption became effective on October 4, 1981.

2. *The date the application was initially submitted with respect to the human drug product under section 507 of the Federal Food, Drug, and Cosmetic Act:* January 20, 1984. FDA verified the applicant's claim that the new drug application for the drug (NDA 50-588) was initially submitted on January 20, 1984.

3. *The date the application was approved:* December 27, 1985. FDA verified the applicant's claim that NDA 50-588 was approved on December 27, 1985.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 598 days of patent extension.

Anyone with knowledge that any of the dates as published in incorrect may, on or before June 9, 1986, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before October 6, 1986, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d Sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1986.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 86-7723 Filed 4-7-86; 8:45 am]

BILLING CODE 4160-01-M

Advisory Committees; Meetings

Correction

In FR Doc. 86-6953, appearing on page 10930, in the issue of Monday, March 31, 1986, make the following corrections.

In the second column, second complete paragraph from bottom, second line, "April 24" should read "April 25".

BILLING CODE 1505-01-M

[Docket No. 86M-0066]

CooperVision, Inc.; Premarket Approval of the QwikCare ™ System

Correction

In FR Doc. 86-5296, beginning on page 8560, in the issue of Wednesday, March 12, 1986, make the following corrections:

1. On page 8560, third column, in the heading, second line, after "QuikCare", "TH" should read "™".

2. On the same page, under For Further Information Contact, "Georgia" was misspelled.

3. On the same page, under Supplementary Information, in the fifth and sixth line, after "QuikCare", "TH" should read "™".